

SEP 20 2011

510 (k) Summary

510(k) Summary: **K101356**

Official correspondent: CHRISTINE L. BRAUER, PH.D.
US AGENT

Manufacturer/Submitter: TECRES S.P.A.
VIA A. DORIA 6
37066 SOMMACAMPAGNA
VERONA - ITALY

FDA OWNER/OPERATOR ID #: 9033624

Date: SEPTEMBER 14, 2011

Trade/Proprietary model names: SPACER-G AND SPACER-K
TEMPORARY HIP AND KNEE PROSTHESIS

Common name: TEMPORARY HIP AND KNEE SPACER WITH GENTAMICIN

Device classification name: PROSTHESIS, HIP, HEMI-, FEMORAL, METAL
PROSTHESIS, KNEE, PATELLOFEMOROTIBIAL, SEMI-
CONSTRAINED, CEMENTED, POLYMER/METAL/POLYMER

Regulation number: 888.3360 AND 888.3560

Device class: II

Classification panel: ORTHOPAEDIC

Classification Product Code: KWL, KWY, AND JWH

DEVICE DESCRIPTION:

Spacers are temporary joint prostheses. Spacer-G is a single piece device that mimics a hemi-hip prosthesis, and is available in six sizes. Spacer-K includes a femoral and tibial component, and is available in three sizes. Spacer-G and Spacer-K are made of fully formed polymethylmethacrylate (radiopaque PMMA with gentamicin). Spacer-G contains an inner stainless steel (AISI 316L stainless steel) reinforcing structure. The mass used in the filling of the molds (the PMMA unformed resin) is prepared from a powder component and a liquid component. The liquid component consists of methylmethacrylate, N,N-dimethyl-p-toluidine, hydroquinone; the powder component consists of polymethylmethacrylate, barium sulphate, benzoyl peroxide, and gentamicin sulphate.

The Spacer devices provide patients, undergoing a two-stage revision procedure for an infected total joint, a temporary implant to 1) allow for partial weight bearing and 2) provide a natural range of motion. The devices also maintain a patient's soft tissue and joint space, preventing further complications such as muscular contraction. The gentamicin protects the device from bacterial colonization.

INTENDED USE AND INDICATIONS FOR USE:

Spacer-G and Spacer-K are indicated for temporary use (maximum 180 days) as a total hip or knee replacement for patients undergoing a two-stage procedure due to a septic process. The indications for use are provided below.

Spacer-K

Spacer-K is indicated for temporary use (maximum of 180 days) as a total knee replacement (TKR) in skeletally mature patients undergoing a two-stage procedure due to a septic process.

Spacer-K is applied on the femoral condyles and on the tibial plate following removal of the existing implant and radical debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

Spacer-K is not intended for use for more than 180 days, at which time it must be explanted and permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.). Because of the inherent mechanical limitations of the device material (gentamicin/polymethylmethacrylate), Spacer-K is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

Spacer-G

Spacer-G is indicated for temporary use (maximum of 180 days) as a total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process.

The device is inserted into the femoral medullary canal and acetabular cavity following removal of the existing implant and radical debridement. The device is intended for use in

conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

Spacer-G is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.).

SUBSTANTIAL EQUIVALENCE:

The Spacer devices are substantially equivalent to themselves. Each Spacer device has previously been cleared: Spacer-K in K062274 and, Spacer-G in K062273. The intended use and conditions of use remain the same. This 510(k) application was submitted for a minor change in the materials in each Spacer device.

Performance testing was conducted to verify that implant performance continues to meet the production specifications and be adequate for in vivo applications under the temporary conditions of use. Mechanical properties, gentamicin release and stability data were evaluated and found to support the substantial equivalence of the devices.

Based on the same fundamental scientific technology and on the results of the verification activities, it is concluded that the modified Tecres Spacer devices are substantially equivalent to the legally marketed Tecres Spacer devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

TECRES SPA
% Christine Brauer, Ph.D.
Brauer Device Consultants, LLC
7 Trailhouse Court
Rockville, Maryland 20850

SEP 20 2011

Re: K101356

Trade/Device Name: Tecres Spacer-G
Regulation Number: 21 CFR 888.3360
Regulation Name: Prosthesis, hip, hemi-, femoral, metal
Regulatory Class: Class II
Product Code: KWL, KWY, and MBB

Trade/Device Name: Tecres Spacer-K
Regulation Number: 21 CFR 888.3560
Regulation Name: Prosthesis, knee, patellofemorotibial, semi-constrained, cemented,
polymer/metal/polymer
Regulatory Class: Class II
Product Code: JWH and MBB

Dated: July 27, 2010

Received: July 28, 2010

Dear Dr. Brauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2

Indications for Use Form

510(k) Number (if known): K101356

Device Name: Spacer-K and Spacer-G

Indications for Use:

Spacer-K

Spacer-K is indicated for temporary use (maximum of 180 days) as a total knee replacement (TKR) in skeletally mature patients undergoing a two-stage procedure due to a septic process.

Interspace is applied on the femoral condyles and on the tibial plate following removal of the existing implant and radical debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

Spacer-K is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.). Because of the inherent mechanical limitations of the device material (gentamicin/polymethylmethacrylate), Spacer K is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

Spacer-G

Spacer-G is indicated for temporary use (maximum of 180 days) as a total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process.

The device is inserted into the femoral medullary canal and acetabular cavity following removal of the existing implant and radical debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

Spacer-G is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101356

Concurrence of CDRH, Office of Device Evaluation (ODE)